



CTMS Adverse Events Reporting SIG Teleconference Meeting Minutes

Meeting Date	Friday, October 1, 2004 3:00 – 4:00 PM EDT																																																			
Attendees:	<p>Working group coordinator: Scott Finley (Booz Allen Hamilton) Harshawardhan Bal (Booz Allen Hamilton)</p> <p>Participants:</p> <table><tr><td>Name</td><td>Email</td><td>Center</td></tr><tr><td>Joyce Niland (SIG lead)</td><td>jniland@coh.org</td><td>City of Hope</td></tr><tr><td>Amy Cox</td><td>acox@coh.org</td><td>City of Hope</td></tr><tr><td>Andrea Hwang</td><td>ychwang@uci.edu</td><td>UC Irvine</td></tr><tr><td>Bob Morrell</td><td>bmorrell@wfubmc.edu</td><td>Wake Forest</td></tr><tr><td>David Rose</td><td>David.Rose@med.va.org</td><td>VA</td></tr><tr><td>Diane Paul</td><td>funnylady93@earthlink.net</td><td>CARRA</td></tr><tr><td>Doug Fridsma</td><td>fridsma@cbmi.pitt.edu</td><td>UPMC</td></tr><tr><td>Erin Iturriaga</td><td>iturriae@mail.nih.gov</td><td>DCP</td></tr><tr><td>Hemant Shah</td><td>hshah@coh.org</td><td>City of Hope</td></tr><tr><td>John Speakman</td><td>speakman@biost.mskcc.org</td><td>Sloan-Kettering</td></tr><tr><td>Linda Parreco</td><td>parrecol@mail.nih.gov</td><td>DCP</td></tr><tr><td>Rhoda Arzoomanian</td><td>rza@medicine.wisc.edu</td><td>Wisconsin</td></tr><tr><td>Sharon Elcombe</td><td>elcombe@mayo.edu</td><td>Mayo Clinic</td></tr><tr><td>Sorena Nadaf</td><td>s.nadaf@vanderbilt.edu</td><td>Vanderbilt</td></tr><tr><td>Susan Pannoni</td><td>pannonis@coh.org</td><td>City of Hope</td></tr><tr><td>Valerie Monaco</td><td>monacov@upmc.edu</td><td>UPMC</td></tr></table>	Name	Email	Center	Joyce Niland (SIG lead)	jniland@coh.org	City of Hope	Amy Cox	acox@coh.org	City of Hope	Andrea Hwang	ychwang@uci.edu	UC Irvine	Bob Morrell	bmorrell@wfubmc.edu	Wake Forest	David Rose	David.Rose@med.va.org	VA	Diane Paul	funnylady93@earthlink.net	CARRA	Doug Fridsma	fridsma@cbmi.pitt.edu	UPMC	Erin Iturriaga	iturriae@mail.nih.gov	DCP	Hemant Shah	hshah@coh.org	City of Hope	John Speakman	speakman@biost.mskcc.org	Sloan-Kettering	Linda Parreco	parrecol@mail.nih.gov	DCP	Rhoda Arzoomanian	rza@medicine.wisc.edu	Wisconsin	Sharon Elcombe	elcombe@mayo.edu	Mayo Clinic	Sorena Nadaf	s.nadaf@vanderbilt.edu	Vanderbilt	Susan Pannoni	pannonis@coh.org	City of Hope	Valerie Monaco	monacov@upmc.edu	UPMC
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Agenda	<p>I. Review of Minutes: September 17, 2004</p> <p>II. DCP IND Studies SAE Reporting Process Diagram (Amy Cox – COH)</p> <p>III. CaBIG AE, CTMS-CDUS Survey Summary Review: Updated Results (Dr. Niland – COH)</p> <p>IV. Scope of the caBIG AE System A. SAE System vs. B. AE Reporting System with SAE components</p>																																																			

**General discussion
points raised by
participants:**

- V. NCI's Central IRB
 - A. Discuss the Role of NCI's Central IRB
 - B. Should an NCI Central IRB representative participate in the AE SIG teleconferences?
- VI. CaBIG CTMS Quarterly In-Person Meeting: Proposed Agenda Items:
 - A. Use Case Review
 - B. Specification for Structured Protocol
 - 1. Summary IV (2-3 hours)
 - 2. AERS (2-3 hours)
- VII. Transitioning Responsibility of Meeting Minutes:
Designate an AE SIG Participant
- VIII. Next Teleconference: October 15, 2004

Meeting minutes for September 17, 2004, accepted without amendments.

Amy Cox reviewed DCP's SAE Reporting Process when DCP holds the IND. The caBIG AE System will need to be flexible to incorporate the various routing possibilities that exist within an institution and agency such as DCP. Bob Morrell described how his institution's system routes the AE.

Amy Cox provided an update of the AE, CTMS-CDUS survey summary, as a few additional institutions had responded. Amy reported that approximately 25% of the respondents do not have studies that require CTMS and/or CDUS reporting. Meeting participants were provided with the full comments from the survey to review and discuss – at the present time no one had any comments they wished to discuss in more detail.

The scope of the caBIG AE System was addressed. Preferably, the system would be one in which the AE is reported and identified as an AE or an SAE and then routed appropriately. The group discussed subjective grading and persons not grading appropriately based on the amount of reporting that it would require. Further, the group discussed the importance of the QC process for the data entered into the system, as well as how the system would ideally interface with other systems as applicable, to avoid duplicate data entry.

NCI's Central IRB and its potential role within the caBIG project were considered. Sharon Elcombe with Mayo will initiate contact/discussion with the NCI Central IRB via Jaci Goldberg, Project Manager. Amy Cox, COH, will research the NCI Central IRB Website and conduct an interview with the NCI Central IRB contact person as applicable.

Planning continued for the caBIG CTMS Quarterly In-Person Meeting at COH in November. Scott Finley is working on the tentative agenda and

Action items:	<p>will distribute it for comments. The group agreed that the AE SIG would plan to meet during the in-person meeting to review the Use Cases.</p> <p>BAH is transferring responsibility of meeting organization/coordinating to the individual working groups. At this time, no one has volunteered to take minutes and format for distribution.</p> <p>Scott Finley requested that he and Joyce Niland be cc'd on all communications outside of the group, in order to ensure that they are kept current with issues related to this working group.</p> <p>Next teleconference is scheduled for October 15, 2004.</p>
	<p>Initiate contact/discussion with the NCI Central IRB via Jaci Goldberg, Project Manager (Sharon Elcombe of Mayo Clinic).</p> <p>Research the NCI Central IRB Website and conduct an interview with the NCI Central IRB contact person as applicable (Amy Cox of COH).</p> <p>A tentative agenda is being drafted for the CTMS Quarterly in-person meeting, which will be distributed for comments and feedback (Scott Finley).</p> <p>All communications outside of the group will include cc'ing Scott Finley and Joyce Niland, as working group coordinator and working group leader.</p>